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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,068	FISHER ET AL.	
	Examiner	Art Unit	
	CELENE MOORER	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/15/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/19/2009* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 1-6, and 11 are objected to because of the following informalities: The abbreviation CBC should be replaced with its full written name to make it more understandable. Claims 15-17 are objected to because of the following informalities: The abbreviation SGF should be replaced with its full written name to make it more understandable. Appropriate correction is required.

Information Disclosure Statement

2. The information disclosure statement filed 2/19/2009 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-14 and 18-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention does not have a structure and is an abstract idea which can be performed mentally; therefore, it does not fall within at least one of the four categories of patent eligible subject matter recited in 35 U.S.C. 101.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following listed are examples of the problems issues found and applicant is advised to check all the claims to ensure that no 112 2nd paragraph problems exist. Regarding claim 1,12 and 16, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Regarding claims 1, 2, 3, 8, 12 and 19, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). Regarding claim 8, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Claims 4-6 use the phrase “as described herein” which renders the claim indefinite because it is unclear whether the limitation prior to the phrase are part of the claimed invention. It is unclear as to the structure of the “balloon valve” as recited in claims 15-17. It is also unclear as to how a tank of compressed air can open or close the balloon valves as recited in claim 17. Claims 15-17 recite several limitations that have insufficient antecedent basis for these limitations in the claims. The following listed are examples of some of the problems found and applicant is advised to

check each of these claims thoroughly to ensure that no lack of antecedent basis problems exist. Claim 15 recites the limitations "the patient port", the " the gas reservoir" in the 2nd paragraph of the claim and recites the limitations "the balloon valve", "the SGF gas reservoir box", "the differential pressure", "the opening pressure", and "the valve" in the 4th and 5th paragraph of the claim. Claim 17 recites the limitations "the fresh gas reservoir", "inspiratory valve", and "expiratory valve" throughout the claim. Furthermore, regarding claims 15-17, the components of the structures as recited in the claim language are not connected, therefore, it is unclear as to how the invention works. Regarding claim 19, applicant refers to the method of claim 1, 2, 11, 15, 16 or 17, however, it is unclear as to how this claim can refer back to either claims 15, 16, or 17, since these are apparatus claims.

7. Regarding claim 16, there are several 35 USC 112, second paragraph issues throughout all of the claims. It is not clear as to the structure the applicant is trying to claim in the 9th thru 15th line of the claim since applicant refers to a bypass limb that contains a one-way valve, but also refers to the direction of the opening of the valve along with the expiratory and inspiratory limbs being extended by tubing of variable lengths yet the expiratory and inspiratory reservoirs are enclosed in a box with 3 ports. It is also unclear to how the port communicates with the box when inspiratory and expiratory reservoirs are enclosed in a box with 3 ports as recited in lines 15 and 16. It is unclear as to how the inspiratory reservoir is compressed and collapsed as recited in lines 26 and 27. It is unclear as to how the SGF reservoir is expanded as recited in line 38. It is also unclear as to what the structure of the mushroom valve is as recited in line

21. There are several insufficient antecedent basis problems within the claim such as the limitation “port”, “expired gases”, and “expired gas reservoir” in line 6 and 7; the limitation “an opening pressure of the valve” in line 10; the limitation “direction of opening of the one-way valve” in line 12; the limitation “tubing of variable lengths” in line 14; the limitation “the interior of the SGF reservoir” in lines 16 and 17; the limitation "the SGF reservoir” in lines 16-18; the limitation “the ventilator circuit expiratory port”, “the inspiratory phase", and "the box ventilator port" in lines 12 and 22; the limitation "the tidal volume of the ventilator" in line 23; the limitation “the time during inspiration in line 21; the limitation “the total tidal volume” in line 30; the limitation “the expiratory reservoir bag” in line 34; and the limitation "Ve-Vdan" in line 40 of the claim. Applicant is advised to thoroughly check all the claims to ensure that there aren’t any 112 2nd paragraph problems exist. No art rejection will be given since claimed structure is missing and not clearly understood.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-10 and 18-19 as best understood are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication 2002/0020410 A1 to *Rydin et al*.

As to claims 1-10 and 18-19, *Rydin* teaches a method of calculating the flux of any gas (x) in a breathing circuit (CBC circuit) for a ventilated breathing subject (Paragraph 0028, Lines 1-4; Paragraph 0032, Lines 1-9). In regards to claims 1 and 2, the breathing circuit as disclosed by *Rydin* is considered a CBC circuit since applicant indicates breathing circuit (CBC circuit) in these claims. *Rydin* discloses a patient ventilator (2) with a gas flow control unit that provides control signals to regulate the flow of inspiration and expiration gases (Paragraph 0029, Lines 8-11), however, *Rydin* does not expressly discloses that the source of gas flow (via the ventilator) into the breathing circuit could be set by the anesthesiologist. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify *Rydin's* circuit so that the source of gas flow (via the ventilator) into the breathing circuit could be set by the anesthesiologist in order to provide controllable inspiration and expiration phases during one or more control modes of the ventilator (Paragraph 0029, Lines 12-14). *Rydin* does not expressly teach the formulas for calculating the flux of as in a CBC circuit as disclosed by the applicant, however, it would have been obvious to one of ordinary skill in the art at the time of the invention was made that *Rydin's* circuit is capable of calculating the flux of gas using the formula as disclosed by the applicant in order to develop a relationship between the flux of gas and gas flow in the breathing circuit (Paragraph 0009, Lines 1-9). As to claim 2, *Rydin* does not expressly disclose that the method for calculating the flux in a CBC circuit is for oxygen, however, it would have been obvious to one ordinary skill in the art at the time the invention was made that *Rydin's* circuit is capable of calculating the flux of oxygen since oxygen is a gas that

can be supplied to the patient by the ventilator since *Rydin* can determine measured values associated with the pressure or gas flow for either inspiration gas or expiration gas (Paragraph 0032, Lines 5-9). As to claims 3-6, *Rydin* discloses that the method is used in a breathing circuit (Paragraph 0028, Lines 1-4), however, *Rydin* does not expressly disclose that the CBC circuit is an improved Magill circuit, an improved rebreathing circuit, and an improved non-rebreathing circuit. It would have been obvious at the time the invention was made that *Rydin's* circuit could comprise either one of these CBC circuits since they all would appear to work equally as well for providing gas to a ventilated breathing subject as in the breathing circuit taught by *Rydin*. As to claims 7-10, *Rydin* does not expressly teach that the method of claim 2 can be used to determine and optimize oxygen consumption and used as an early indication of malignant hyperthermia. It would have been obvious to one of ordinary skill in the art at the time the invention was made that *Rydin's* circuit is capable of determining and optimizing oxygen consumption and can be used as an early indication of malignant hyperthermia in order to measure oxygen in the breathing circuit and make appropriate oxygen flow adjustments in accordance with flow measurements taken. As to claim 18, *Rydin* does not expressly teach that the method of claim 1 is used to calculate the rate of elimination of a gas X for any input total gas flow using the formula as disclosed in claim 18. It would have been obvious to one of ordinary skill in the art at the time the invention was made that *Rydin's* circuit is capable of calculating the rate of elimination of a gas X for any input total gas flow using the formula as disclosed by the applicant since *Rydin* is able to measure various flow values for the inspiration and

expiration gas of the breathing circuit which is needed in order to calculate the rate of elimination of the gas. As to claim 19, *Rydin* discloses that the method of claim 1 is incorporated on a memory device which is capable of running on a computing device (30) (Paragraph 0036, Lines 33-43).

10. Claim 11-14 as best understood are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication 2002/0014236 A1 to *Dittmann et al*.

As to claims 11-14, *Dittmann* teaches a method for calculating the flux of gas other then carbon dioxide in a breathing circuit (Paragraph 0012, Lines 3-29) and a breathing circuit (12) comprising a carbon dioxide absorber (13). In regards to claim 11, the breathing circuit (12) as disclosed by *Dittmann* is considered a CBC circuit since applicant indicates breathing circuit (CBC circuit) in these claims. *Dittmann* does not expressly disclose a CBC circuit with low gas flow of source gas using the formula as recited in claim 11. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify *Dittmann's* circuit so that it can calculate of any gas even with low gas flow of source gas with a carbon dioxide absorber in place using the formula as recited in claim 11 in order to determine the change in flux of any gas. As to claim 12, *Dittmann* teaches that the method of claim 11 is used to determine the flux of an anesthetic (Paragraph 0037, Lines 1-20). As to claim 13, *Dittmann* teaches the method of claim 12 is used to determine how much anesthetic is absorbed by the patient (Paragraph 0008, Lines 11-24). As to claim 14, *Dittmann* does not expressly disclose that the anesthetic is N_2O, however, it would have been obvious to one of

ordinary skill at the time the invention was made that *Dittmann's* circuit is capable of measuring the anesthetic N_2O since it is a well-known anesthetic gas in the art.

11. Claim 15 as best understood is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,883,051 to *Westenskow et al*.

Regarding claim 15, *Westenskow* discloses an improved Magill circuit (12) the improvement comprising an inspiratory (40) and expiratory (48) limbs, a pressure relief valve (42) at the end of the expiratory limb (48), a port (46) for entry of SGF, and a gas reservoir bag (32), the components of the Magill system utilized for controlled ventilation (Column 2, Lines 48-55), the gas reservoir bag (32) is enclosed in a container (34) with a port (26) connected to a ventilator breathing circuit (12), the pressure relief valve (42) is enclosed in a container (box housing surrounding 42 in Figure 1) with a port (tubing connected to 42 on right side as seen in Figure 1) for connection to a ventilator breathing circuit (12). *Westenskow* lacks a detailed description on the claimed functional recitations. However, since *Westenskow* has the same structure as claimed, the *Westenskow* circuit would be able to perform the recited functions. Regarding the claimed formula, *Westenskow* lacks a detailed description on the formula, however, since *Westenskow* has the computer/controller, it would have been obvious to one of ordinary skill in the art upon seeing *Westenskow's* system, would be able to calculate the desired information. The feature of choosing a particular formula is considered a design choice since it appears that

Westenskow's system would be able to be used to apply such a formula. Note that no patentable weight will be given to the intended use of the device.

12. Claim 17 as best understood is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,581,599 B1 to *Stenzler* in view of US Patent Application Publication 2002/0020410 A1 to *Rydin et al*.

As to claim 17, *Stenzler* discloses a non rebreathing circuit (Figure 1), the improvement comprising a valve circuit (32, 30 are valves in breathing circuit) for spontaneous ventilation of a patient breathing spontaneously (Column 4, Lines 48-50), said circuit having a Y-piece (12) with a patient port (connection between 12 and 14), an inspiratory limb (8) including a valve (30), connected to SGF (22) and a gas reservoir (24), an expiratory limb (10) with an expiratory gas reservoir (18), which has a port opening to the atmosphere (16), a tank of compressed air (24) flows thru the valves (32) to open or close the valves (30), the valves (32) being controlled electronically by a computer (36), the computer for receiving the signal (38) and sending a signal to the valve (32) to close the inspiratory valve (30), the fresh gas flow continuously filling the fresh gas reservoir (24). *Stenzler* does not expressly disclose that the expiratory limb consists of a valve.

Rydin discloses a breathing circuit with an inspiratory limb (10) with an inspiratory valve (14) and an expiratory limb (12) with an expiratory valve (16) and a pressure transducer (34) connected to a mouthpiece (24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify *Stenzler's* breathing circuit to include an expiratory valve in the

expiratory limb and a pressure transducer connected to a mouthpiece as taught by *Rydin* in order to provide more control over the expiratory limb and sense flow from the mouthpiece into the circuit. The modified *Stenzler* reference discloses that the valves are controlled by a computer (*Stenzler*, Column 9, Lines 60-63), it would have been obvious to one of ordinary skill in the art upon seeing *Stenzler* that the circuit could comprise solenoid valves being electronically controlled by a computer. It would have been an obvious matter of design choice to use solenoid valves since applicant has not disclosed that solenoid valves solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the valves as disclosed by *Rydin* and *Stenzler*. The modified *Stenzler* reference discloses that the circuit comprises a fresh gas reservoir (24 in Figure 1 of *Stenzler*); however, the modified *Stenzler* reference does not expressly disclose that the reservoir is fully collapsible. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify *Stenzler*'s circuit to include a fully collapsible reservoir in order to make a more compact breathing circuit.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 5,320,093 to *Ramer* discloses a similar breathing circuit as in claims 15 and 17. US Patent No. 5,806,513 to *Tham et al.* discloses a similar breathing circuit as in claim 15. US Patent No. 5,660,171 to *Kimm et al.* discloses a similar method as in claims 1-14 and 18-19.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELENE MOORER whose telephone number is (571)270-7411. The examiner can normally be reached on M-F 7:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CELENE MOORER/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771